

B7C Sub 1010
ii) 3-20% solid [an] alkali metal carbonate or bicarbonate by weight of the dosage form [in an amount such that];

said solid alkali metal carbonate or bicarbonate being in homogeneous admixture with said ibuprofen medicament and said compressible filler component with disintegrating component,

wherein the dosage form has a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes,

provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

2. (Amended) A dosage form according to claim 1 wherein the racemic ibuprofen medicament is in the form of a salt of ibuprofen.

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4. (Amended) A dosage form according to claim 1 comprising a compressible filler component and up to 15% of a discrete disintegrant component by weight of the dosage form.

5. (Amended) A dosage form according to claim 1 comprising 5-15% [w/w] alkali metal carbonate or bicarbonate by weight of the dosage form.

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7. (Amended) A dosage form according to claim 6 comprising sodium carbonate or bicarbonate in a weight ratio to the racemic ibuprofen medicament of 1:2 to 1:10.

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9. (Amended) A dosage form according to claim 1 wherein the disintegrating component [disintegrant] comprises croscarmellose sodium, sodium starch glycollate or mixtures thereof.

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11. (Amended) A method of preparing a solid non-effervescent dosage form suitable for oral administration of a sodium salt of racemic [an] ibuprofen [medicament] comprising the steps of:

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mixing a carrier material with the ibuprofen medicament under dry conditions, wherein the carrier material comprises 3-20% [an] alkali metal carbonate or bicarbonate by weight of the dosage form, 10-50% [a] compressible filler component by weight of the dosage form and up to 15% of a disintegrating component by weight of the dosage form to obtain a mixture and then compressing said mixture into a solid non-effervescent dosage form having a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes, wherein the sodium salt of racemic ibuprofen [medicament] comprises at least 35% by weight of the dosage form.

12. (Amended) The method according to claim 11 wherein the dosage form comprises 40-60% sodium salt of racemic ibuprofen by weight of the dosage form [medicament is in the form of the sodium salt].

13. (Amended) The method according to claim 11 wherein the carrier material is adapted for direct compression with [the] said sodium salt of racemic ibuprofen

[medicament] into a tablet.

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14. (Amended) The method according to claim [11] 12 to prepare a tablet wherein [the ibuprofen medicament is the sodium salt of ibuprofen,] the compressible filler component comprises microcrystalline cellulose and the alkali metal carbonate or bicarbonate is sodium carbonate or bicarbonate.

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16. (Amended) A method of obtaining an onset-hastened analgesic and/or anti-pyretic response comprising the oral administration of a non-effervescent compressed solid dosage form comprising 35% or more by weight of a racemic [an] ibuprofen medicament together with a carrier material comprising

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i) a compressible filler component combined with a disintegrating component, and
ii) 3-20% solid [an] alkali metal carbonate or bicarbonate by weight of the dosage form,

said solid alkali metal carbonate or bicarbonate being in homogeneous admixture with said ibuprofen medicament and said compressible filler component with disintegrating component.

wherein the dosage form has [having] a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes,

provided that the ibuprofen medicament does not include a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

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18. (Amended) A method according to claim 16 [15] wherein the solid dosage form

has a disintegration time in the range 1-5 minutes.

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19. (Amended) A method according to claim 16 wherein the dosage form is in the form of a directly compressed tablet comprising 40-85% [w/w] sodium salt of ibuprofen by weight of the dosage form and 5-15% [w/w] sodium carbonate or bicarbonate by weight of the dosage form.

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20. (Amended) A process to prepare a non-effervescent solid dosage form suitable for oral administration comprising [an] a racemic ibuprofen medicament present to an extent of 35% or more by weight of the dosage form characterised by combining [and] a carrier material comprising 8-80% [a] compressible filler component by weight of the carrier [combined with a] 10-20% disintegrating component by weight of the carrier, [characterised by combining the carrier material incorporating an] 8-40% alkali metal carbonate or bicarbonate by weight of the carrier, with the ibuprofen medicament to form a homogeneous solid mixture under dry conditions optionally with other tableting excipients and compressing the mixture into one or more solid dosage forms having a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes.

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22. (Amended) A process according to claim 20 wherein the carrier material comprises an [a] inert diluent component.

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25. (Amended) A process according to claim 20 [19] wherein the ratio of ibuprofen

medicament to the carrier material is in the range 2:1 to 1:2 parts by weight and the carrier material comprises 5-20% [w/w] sodium carbonate or bicarbonate by weight of the dosage form.

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26. (Amended) A solid formulation having a layer comprising a composition comprising [an] a racemic ibuprofen medicament together with a carrier material, the racemic ibuprofen medicament being present to an extent of 35% or more by weight of the composition and the carrier material comprising a compressible filler component combined with a disintegrating component characterised in that the carrier material comprises 3-20% solid [an] alkali metal carbonate or bicarbonate by weight of the dosage form.

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said solid alkali metal carbonate or bicarbonate being in homogeneous admixture with said ibuprofen medicament and said compressible filler component with disintegrating component.

wherein [in an amount such that] the composition is capable of compression to provide a layer having a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes.

Please add claims 27-37 as follows.

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27. (New) A dosage form according to claim 1 comprising up to 20% by weight of an inert diluent component.

28. (New) A dosage form according to claim 1 comprising 0-10% by weight of an inert

diluent component.

29. (New) A dosage form according to claim 1 consisting essentially of a powder mixture of a racemic ibuprofen medicament, compressible filler component, a discrete disintegrating component and an alkali metal carbonate or bicarbonate.

30. (New) A dosage form according to claim 3 in the form of a compressed tablet comprising 40-60% sodium salt of ibuprofen by weight of the dosage form, 20-50% one or more compressible fillers by weight of the dosage form, up to 10% of a disintegrant component by weight of the dosage form selected from croscarmellose sodium and sodium starch glycolate, 4-16% of sodium carbonate or bicarbonate by weight of the dosage form, up to 4% lubricant by weight of the dosage form and up to 2% flow aid by weight of the dosage form.

31. (New) A dosage form according to claim 3 wherein the compressible filler component is selected from one or more of methyl cellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, microcrystalline cellulose, hydroxypropylmethyl cellulose, hydroxymethylpropyl cellulose phthalate, lactose, sucrose, dextrin, sodium chloride, mannitol, sorbitol, cyclodextrin, maltodextrin, calcium phosphate and calcium sulphate.

32. (New) The method according to claim 11 further incorporating the addition of up to 20% by weight of an inert diluent.

33. (New) The method according to claim 11 wherein the tablet comprises 40-60% sodium salt of racemic ibuprofen by weight of the dosage form, 20-50% compressible filler component by weight of the dosage form, up to 10% disintegrating agent by weight of the dosage form, 4-16% sodium carbonate by weight of the dosage form, up to 4% stearic acid, calcium stearate or magnesium stearate by weight of the dosage form and up to 2% colloidal silicon dioxide by weight of the dosage form.

34. (New) The method according to claim 12 to prepare a directly compressed tablet comprising 40-85% w/w sodium salt of racemic ibuprofen and 5-15% w/w sodium carbonate or bicarbonate.

35. (New) The method according to claim 11 wherein the dosage form has a crushing strength in the range 8-12Kp at a compression force in the range 100-140MPa.

36. (New) The method according to claim 11 wherein the solid dosage form has a disintegration time in the range of up to 5 minutes.

37. (New) A process according to claim 20 wherein the solid dosage form has a crushing strength in the range 8-12Kp when compressed at a compression force in the range 100-140Mpa. --
